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Jacinda de Witts
Deputy Secretary, People, Operations, Legal and Regulation Division
Department of Health
50 Lonsdale Street
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19 April 2024

Dear Ms de Witts

REGULATORY IMPACT STATEMENT FOR THE HEALTH SERVICES (HEALTH SERVICE ESTABLISHMENTS) REGULATIONS 2024

I would like to thank your staff at the Department of Health (the Department) for working with the team at Better Regulation Victoria on the preparation of the Regulatory Impact Statement (RIS) for the Health Services (Health Service Establishments) Regulations 2024 (the proposed Regulations).

As you know, the Commissioner for Better Regulation is required to provide independent advice on the adequacy of the analysis provided in all RISs in Victoria. A RIS is deemed to be adequate when it contains analysis that is logical, draws on relevant evidence, is transparent about any assumptions made, and is proportionate to the proposal's expected effects. The RIS also needs to be clearly written so that it can be a suitable basis for public consultation.

I am pleased to advise that the final version of the RIS received by us on 19 April 2024 meets the adequacy requirements set out in the *Subordinate Legislation Act 1994*.

Background and Problems

Private hospitals, day procedure centres and mobile health services (collectively known as health services establishments - HSEs) play a significant role in healthcare delivery in Victoria. In 2021-22, HSEs delivered one million episodes of care (called separations), equivalent to around 37 per cent of all hospital separations in Victoria, with private hospitals delivering 70 per cent of all planned surgeries across Australia. HSEs allow patients to elect to pay for services (typically drawing on private health insurance) in

order to receive faster access to services or exercise greater choice regarding clinicians or facilities. Most HSEs operate as private businesses, although around a third of private hospitals are administered on a not-for-profit basis by religious, charitable or community organisations. As of November 2023, there were 76 private hospitals, 97 day procedure centres and 28 mobile anaesthesia services registered in Victoria.

The Department explains in the RIS that regulation is needed to ensure that healthcare services have appropriate systems and processes in place to identify and minimise risk. This is because the provision of healthcare services carries higher risks and potential for adverse outcomes than many other goods and services. Patients also generally have less information than service providers, given the specialist knowledge and complexity inherent in healthcare services.

The *Health Services Act 1988* (the Act) provides the legislative framework governing health services in Victoria. The Health Services (Health Service Establishments) Regulations 2013 (the current Regulations) are made under the Act. The current Regulations specify quality and safety standards for patient care in HSEs that, along with the Australian Health Service Safety and Quality Accreditation Scheme, are intended to safeguard patients from risk of serious harm. The current Regulations set requirements for HSEs relating to:

- documenting clinical governance
- procedures for record-keeping and complaint handling
- staffing levels, and the qualifications and competency of staff
- standards for premises and equipment
- reporting data and information to the Secretary of the Department (the Secretary)
- ensuring care is patient-centred including providing information.

The current Regulations are due to sunset on 1 September 2024, having previously been extended for 12 months.

The Department explains that if the current regulations were allowed to sunset without being remade, requirements related to the quality and safety of healthcare would be removed, resulting in increased risk of serious harm to patients in HSEs. Prior to the current regulations sunsetting, the Department conducted a review of the existing requirements informed by stakeholder consultation, which identified four specific problems with the current regulations:

- The existing **clinical governance arrangements,** which define the relationships and responsibilities between an HSE and other key stakeholders**,** do not enable sufficient oversight by the Department.
- There are opportunities to improve the process for the **reporting and review of sentinel events** (defined as an unexpected and adverse event that occurs

infrequently resulting in the death or serious injury to a patient due to system and process deficiencies).

- **The existing admission information and assessment** could be made clearer and has some gaps in coverage. This process is used to identify patient concerns and or/comorbidities (the presence of additional conditions or risk factors).
- The Department cannot draw on **infringement notices** as an enforcement tool as these are not provided for under the current Regulations. The Department explains that this leaves court proceedings as the only available enforcement tool, making ensuring compliance potentially costly and difficult.

Options and Impact Analysis

In the RIS, the Department analyses four key areas of regulation identified in its review:

- clinical governance
- reporting and review of sentinel events
- admissions assessment
- infringement penalties.

The RIS analyses options for each of these areas of regulation including:

- an option to replicate the existing requirements from the current Regulations.
- at least one option to introduce targeted amendments which respond to the problems identified in the Department's review.
  For each area of regulation, these options are compared to a base case under which the current Regulations sunset and the relevant requirements lapse. The Department explains that the base case is included as a point of comparison to analyse the impacts of other options and is not considered a feasible option.

The RIS analyses these options using multi-criteria analysis (MCA). The MCA has two criteria, each weighted at 50 per cent:

- Safety and quality of patient care.
- Cost to HSEs and government.

The options analysed and the preferred options for each element are discussed below.

Clinical Governance

- **Base case: no regulations** — requirements under the current Regulations (specified in Regulation 7A) would no longer apply, however, HSEs would still be required to meet the clinical governance standards under Section 107 of the Act.

- **Option 1: current Regulations** — the requirements in Regulation 7A would be remade with HSEs remaining subject to existing requirements to prepare safety and quality protocols and the current oversight by the Secretary.
- **Option 2: current Regulations plus additional protocols and Secretary oversight** — Regulation 7A would be remade with additional quality and safety protocols and the Secretary's oversight would be enhanced.
- **Option 3: Option 2 plus mandating the Victorian Clinical Governance Framework (VGCF) and Credentialing policy** — in addition to remaking and extending Regulation 7A as per Option 2, the protocols would also mandate the same clinical governance and credentialing guidance as apply to public hospitals (which are currently not mandatory for HSEs).

Option 2 is preferred because it would result in only marginally higher costs than Option 1, whereas Option 3 would entail higher costs than Option 2 without any added benefit.

Sentinel Events

- **Base case: no regulations** — the specific sentinel event reporting requirement under the current Regulations (specified in Regulation 46A) would no longer apply. HSEs would continue to have responsibilities to disclose and analyse incidents under national standards and be subject to a requirement to review any Serious Adverse Patient Safety Event (SAPSE) (of which sentinel events are a sub-category) as well as a duty of candour to impacted parties under the Act.
- **Option 1: current Regulations** — the existing requirement to report sentinel events in writing to the Secretary within a specified timeframe under Regulation 46A would be remade.
- **Option 2: current Regulations plus new event review process requirement and enhanced reporting** — in addition to remaking existing requirements, the form and manner of event reporting would be prescribed (intended to be via the Safer Care Victoria (SCV) online portal) and HSEs would be required to review each sentinel event according to specified process requirements and reporting timeframes (intended to be the Victorian Sentinel Event Guidelines).

The Department identifies Option 2 as the preferred option, explaining that most HSEs currently use the SCV portal and follow the Victorian Sentinel Event Guidelines, but a small number would need to start doing so. The Department explains that additional process and reporting requirements under Option 2 might result in higher costs for some HSEs, but assesses these costs as less significant than the anticipated benefits to patient safety and quality realised through better oversight and process improvements.

Admissions Information and Assessment

- **Base case: no regulations** — the current Regulations requiring a pre-admission clinical risk assessment would lapse, however, HSEs would still have obligations under national standards to assess clinical risks and keep appropriate records.
- **Option 1: current Regulations** — the existing requirement under Section 20A of the current Regulations requiring HSEs to complete a pre-admission clinical risk assessment and maintain relevant records would be remade.
- **Option 2: current Regulations with clarifications and enhanced record-keeping requirements** — the existing requirements under Section 20A would be clarified to explicitly state that the pre-admission assessment must be completed by a registered health practitioner and is required for certain prescribed services for which patients are not formally admitted. Record-keeping obligations would also be strengthened to require matters considered in the assessment to be noted in the assessment, rather than the current requirement to record only the results.

The Department explains that Option 2 is the preferred option, as the benefits of improvements to quality and safety would outweigh the minor additional costs that would be incurred by some HSEs in meeting enhanced obligations.

Infringements

- **Base case: no regulations** — the current Regulations would lapse and no infringements would be prescribed. HSEs would still be subject to offences set out in the Act, which could be enforced through court proceedings.
- **Option 1: current Regulations** — the current Regulations would be remade and set out 36 offences and associated penalty units in addition to those in the Act. No infringements would be prescribed, leaving court proceedings as the only avenue for enforcement.
- **Option 2: current Regulations with the addition of prescribed infringement offences** — the current Regulations would be remade with infringement notices and penalties prescribed to enable infringements to be issued for 27 of the 36 existing offences (selected with reference to the Attorney General's Guidelines to the *Infringements Act 2006*).

The Department identifies Option 2 as the preferred option as it allows a more proactive, efficient, and proportionate approach to enforcing compliance, thereby promoting safety and quality of patient care. The Department notes that HSEs that are compliant with regulatory requirements would not incur costs under any of the enforcement options, and that costs to the Government and HSEs would depend on how the proposed infringement notice approach is implemented.

Administrative Changes and Clarifications

In addition to the four main areas of analysis, the RIS also highlights several proposed administrative changes and clarifications to be introduced in the remade regulations . The Department explains that these changes have not been analysed in the MCA as they are not expected to impose burden. These changes and their anticipated benefits are:

- Enhanced information disclosure requirements to improve transparency about third party fees and services.
- A requirement for HSEs to display accreditation prominently to make this information more evident to consumers.
- Aligning the Regulations with national and state obligations related to gender identity and adopting gender-neutral language to prevent discrimination.
- Updating language to reflect clinical terminology and eliminate potential ambiguity.
- More flexible discharge information requirements for short-term hospital stays to reduce administrative burden on HSEs while maintaining standards of patient care.
- Removal of a provision (scalding prevention) to reduce unnecessary duplication of other legislation and regulations.
- Enhancing Departmental oversight by improving data reporting from mobile health services, record keeping requirements for patient transfers out of an HSE for escalated care, and the ability to review records required to be kept by HSEs.

Fees

The Department explains that the current Regulations prescribe fees charged to HSEs which recover some of the Department's costs in administering the Act and Regulations. The Department estimates that the current fees would recover around 63 per cent (or $900,000) of the Department's relevant costs (estimated at around $1.4 million)

The Department further explains that fee alternatives are evaluated using the Department of Treasury and Finance's *Pricing for Value Guide*. It highlights that this guidance is specifically designed to support decision-making around fees and is more suitable than the MCA for this part of the analysis because fees for HSEs do not directly influence its patient care criterion. The Department notes that setting fees to fully recover costs in line with Pricing Principle 1 would require a uniform fee increase of around 55 per cent. However, it explains that feedback from the sector raised concerns that a uniform fee increase would impose relatively high costs on small HSEs, potentially impacting their ability to pay or resulting in potential unintended consequences of cost-cutting or non-compliance. The Department notes that targeting full cost recovery by imposing higher fees on larger HSEs alone would also be infeasible despite their higher ability to pay, given the relatively small number of large providers. The Department therefore proposes to continue the existing fee structure in the remade regulations,

noting that the precise level of cost recovery may vary with changing fee revenues and costs.

Implementation and Evaluation

The Department states that it will be responsible for implementing the proposed Regulations and outlines an implementation plan involving three key elements:

1. Remaking the regulations including conducting public consultation on draft regulations which include the proposed changes.
2. Developing and implementing the proposed additional oversight of clinical governance through a review of protocols by the Secretary.
3. Communicating with and educating HSEs on the proposed amendments to the Regulations.

The Department outlines its intention to delay the commencement of new provisions by six to twelve months after the new Regulations commence to allow time for the Department and HSEs to prepare for new processes and requirements.

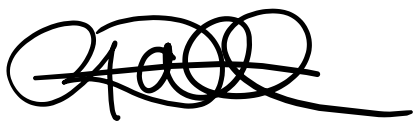
The Department explains that it will continuously monitor the effectiveness and efficiency of the proposed Regulations and undertake a structured evaluation prior to the Regulations sunsetting. The Department's draft evaluation plan includes key evaluation questions related to problem identification, effectiveness and efficiency and outlines existing data sources to establish a baseline for future comparison including:

- the Victorian Admitted Episodes Dataset (VAED)
- quality and safety indicators from SCV, including those developed through proposed amendments to the Regulations supporting enhanced oversight
- site inspections of HSEs
- accreditation data from the Australian Commission on Safety and Quality in Health Care.

The Department explains that the evaluation plan will identify and respond to data gaps.

Should you wish to discuss any issues raised in this letter, please do not hesitate to contact my office on (03) 7005 9772.

Yours sincerely



Cressida Wall

Commissioner for Better Regulation